

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



MEMORANDUM

9/22/2020

SUBJECT: Product Chemistry Review for **PATHCO 5.9** EPA Reg. No.: **93744-R**

FROM: Lindsay O'Dell

Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

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Registrant: Pathcolab, LLC

Action code: A531

Agency Due Date:
11/23/2020

DP No.: 459104

Submission No.: 1054858

E-Sub No.: 52788

Classification: EP

Process: Integrated
system

Pesticide type:
Disinfectant

THRU: Karen P. Hicks, Team Leader (Joseph Williams Jr., PhD
Chemistry and Toxicology Team for KPH)
Product Science Branch
Antimicrobials Division (7510P)

Handwritten signature of Karen P. Hicks in black ink.

TO: Jacqueline Hardy, PM Team 34 / Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

MRID(s):-

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
000595	7722-84-1	Hydrogen peroxide	27.3%
063201	79-21-0	Peroxyacetic acid	5.9%
		Other Ingredients	66.8%
		Total	100%

I. BACKGROUND

The Registrant, Pathcolab, LLC, has submitted an application for pesticide registration for their product: PATHCO 5.9 EPA Reg. No. 93744-R. In the cover letter dated 7/20/2020, the registrant has proposed that the product is identical and substantially similar to 10324-214 Maguard 2526. The proposed product has emerging viral pathogen claims, therefore, qualifies for expedited review. The "CITE-ALL" method of support is used to fulfill the product chemistry data requirements, refer to data matrix dated 7/17/2020.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-27 – Formulator's Exemption Statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EPA FORM 8570-35 – Data Matrix (7/17/2020)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Cover letter (7/20/2020)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Transmittal document	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Proposed CSF BASIC, (7/10/2020)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Proposed label, 7/18/2020	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Certification for Pilot Fragrance Notification Program	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
Comments:		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
Active Ingredients(s)			Nominal	Upper limit	Lower limit
Hydrogen peroxide			27.3%	28.12%	26.48%
Peroxyacetic acid			5.9%	6.2%	5.61%
			YES	NO	N/A
1. The certified limits of all ingredients are within 40 CFR standard certified limits.			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Wider certified limits were requested and rationale was accepted.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. The nominal concentration(s) of the active ingredient is in agreement with the label.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. All inert ingredients are approved for food use pesticide formulations.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The impurities present >0.1% are identified.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Impurities of toxicological significance have an upper certified limit.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

b. Product Label:

	Yes	NO	N/A
<i>The formula contains one of the following:</i>			
1. 10% or more of petroleum distillate	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. 1.0% or more of methyl alcohol	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Sodium nitrite at any level	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. A toxic list 1 inert at any level	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Arsenic in any form	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

IV. Additional Findings

1. Based on the comparison of formulations, the proposed product is not identical to the cited product. This determination was made during a meeting of the Chemistry and Acute Toxicology Science Advisory Council on 9/17/2020.

2. This product is produced by using a registered source of hydrogen peroxide. However, the active ingredient Peracetic acid (PAA) is product *in situ*. A preliminary analysis study must be submitted to fulfill guideline 830.1700 according to 40 CFR 158.3545.

V. Conclusion

The proposed product is not identical to the cited product 10324-214. Group A and Group B product chemistry data requirements have not been met to support the registration of 93744-R, Pathco 5.9.